

Pyloric Endoscopic Myotomy as treatment for patients with symptom of gastric outlet obstruction after oesophagectomy with gastric conduit.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22297

Source

NTR

Brief title

PEMpoco

Health condition

Delayed gastric emptying after oesophagectomy with gastric tube reconstruction.

Sponsors and support

Primary sponsor: None.

Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

1. Efficacy of G-POEM defined as success rate at 3 months, reported as patient reported

outcome measurements (PROMS) using a 6 point likert scale, answer-ing the question: “How do you rate your symptoms after the G-POEM procedure as compared to the situation before the procedure?” 1. symptoms fully disap-peared, 2. significant improvement, 3. mild improvement, 4. no change, 5. bit worse, 6. significantly worse. A score of 1 or 2 is considered clinical success.

2. Feasibility of G-POEM defined as technical success of G-POEM procedure (i.e. the ability to perform a complete pyloromyotomy).

3. Safety of G-POEM based on:

- Peri-operative G-POEM complications: perforation, bleeding, cardiopulmonary events.
- All severe adverse events (SAEs) defined as any unwanted events occurring within 5 days after G-POEM resulting in >72 hours prolonged admission, ad-mission to a medium or intensive care unit, additional unplanned endoscopic procedures, unplanned radiological (e.g. coiling) or surgical interventions, or blood transfusion or death.

Secondary outcome

8.1.2 Secondary study parameters/endpoints

1. Durability of G-POEM, defined as the clinical success rate at 12 months reported as PROMs (see main study parameter 1).

2. Success rate at 3 and 12 months based on:

- Objective parameters: post-G-POEM gastric emptying time on nuclear scintigraphy, post-G-POEM gastric emptying time on barium swallow, post-G-POEM EndoFlip measurement, post-G-POEM gastroduodenoscopy findings.
- Subjective parameters: Gastric Cardinal Symptom Index (GCSI), dumping symptom score, regurgitation symptom score.

3. Possible predictors for success or failure of G-POEM, based on:

- Objective parameters: pre-G-POEM gastric emptying times on nuclear scintig-raphy, pre-G-POEM gastric emptying on barium swallow, pre-G-POEM EndoFlip, pre-G-POEM gastroduodenoscopy (e.g. retention and/or dilation of gastric tube), previous success on BOTOX injection.
- Subjective parameters (patient reported outcomes): Gastric Cardinal Symp-tom Index (GCSI), dumping symptom score, regurgitation symptom score.

4. Adverse events (AEs) defined as any unwanted events that arise following treatment and/or that are secondary to the treatment; events classified as severe adverse events (SAEs) are mentioned as primary endpoint.

5. (changes in) Quality of life, based on SF-36 questionnaire.

Study description

Background summary

The aim of this study is to evaluate the efficacy of endoscopic pyloromyotomy and the value of diagnostic measurements for identifying delayed gastric emptying and as predictive factors for outcome of treatment. We will observe the efficacy of the endoscopic

pyloromyotomy. Patients will undergo an EndoFlip measurement which is not part of routine clinical practice and they will be subject to questionnaires.

Study objective

1. We hypothesise that the G-POEM (endoscopic pyloromyotomy) will be an effective and feasible technique as treatment of delayed gastric emptying.

Study design

1. Main study parameters/endpoints:

- Efficacy of G-POEM defined as success rate at 3 months, reported as patient reported outcome measurements (PROMS) using a 6 point Likert scale, answering the question: "How do you rate your symptoms after the G-POEM procedure as compared to the situation before the procedure?" 1. symptoms fully disappeared, 2. significant improvement, 3. mild improvement, 4. no change, 5. bit worse, 6. significantly worse. A Likert score of 1 or 2 is considered clinical success.

- Feasibility of G-POEM defined as technical success of G-POEM procedure (i.e. the ability to perform a complete pyloromyotomy).

- Safety of G-POEM based on:

- o Peri-operative G-POEM complications: perforation, bleeding, cardiopulmonary events.

- o All severe adverse events (SAEs) defined as any unwanted events occurring within 5 days after G-POEM resulting in >72 hours prolonged admission, admission to a medium or intensive care unit, additional unplanned endoscopic procedures, unplanned radiological (e.g. coiling) or surgical interventions, or blood transfusion or death.

2. Secondary study parameters/endpoints:

- Durability of G-POEM, defined as the clinical success rate at 12 months reported as PROMs (see main study parameter 1).

- Success rate at 3 and 12 months based on:

- o Objective parameters: post-G-POEM gastric emptying time on nuclear scintigraphy, post-G-POEM gastric emptying time on barium swallow, post-G-POEM EndoFlip® measurement, post-G-POEM gastroduodenoscopy findings.

- o Subjective parameters: Gastric Cardinal Symptom Index (GCSI), dumping symptom score, regurgitation symptom score.

- Possible predictors for success or failure of G-POEM, based on:

- o Objective parameters: pre-G-POEM gastric emptying times on nuclear scintigraphy, pre-G-POEM gastric emptying on barium swallow, pre-G-POEM EndoFlip®, pre-G-POEM gastroduodenoscopy (e.g. retention and/or dilation of gastric tube), previous success on BOTOX injection.

- o Subjective parameters (patient reported outcomes): Gastric Cardinal Symptom Index (GCSI), dumping symptom score, regurgitation symptom score.

- Adverse events (AEs) defined as any unwanted events that arise following treatment and/or that are secondary to the treatment; events classified as severe adverse events (SAEs) are mentioned as primary endpoint.

- (changes in) Quality of life, based on SF-36 questionnaire.

Contacts

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Eligibility criteria

Inclusion criteria

1. Previous oesophagectomy with gastric tube reconstruction (>3 months earlier)
2. Age between 18-90 years.
3. Presence of delayed gastric emptying based on symptoms and at least one of the following objective parameters indicating delayed gastric emptying:
 - a. Delayed gastric emptying on nuclear scintigraphy,
 - b. Delayed gastric emptying on timed barium swallow,
 - c. Retention of solids in the gastric tube seen during gastroduodenoscopy, and/or
 - d. Good symptomatic response on botulinum toxin injection into the pylorus (re-sponse lasted at least 2 months).
4. Signed written informed consent.

Exclusion criteria

1. Previous surgical drainage (pyloroplasty or pyloromyotomy).
2. Previous (attempt at) G-POEM.
3. Uncontrolled coagulopathy.
4. Prognosis qua ad vitam <2 years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2020
Enrollment:	33
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description

Data will be handled confidentially. Meaning that personal data will only be handled by the PI and research team of each centre. Data will be collected from different sources (HiX, EndoFlip, Questionnaires) and captured using CASTOR EDC. The data captured in CASTOR will be pseudonymised. The code list of patient identification will only be available for the PI and lead investigators of each site. For more information our Datamangementplan can be consulted.

Ethics review

Positive opinion	
Date:	03-02-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49332
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9808
CCMO	NL70978.041.19
OMON	NL-OMON49332

Study results